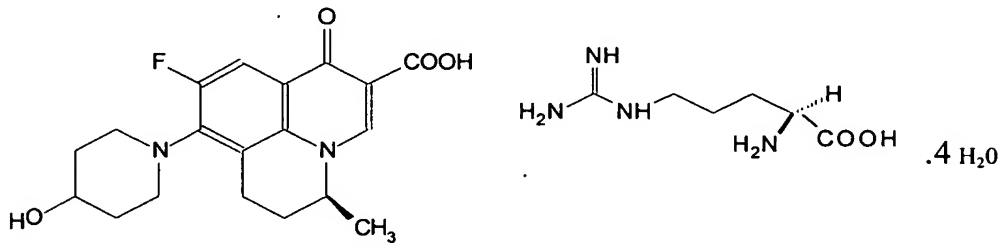
CLAIMS

1. S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate of the formula I



Formula I

in a crystalline form.

2. A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following X-ray powder diffraction data: (2θ):4.86± 0.2,14.10 ± 0.2, 14.90 ± 0.2, 19.35 ± 0.2, 22.20 ± 0.2, 23.04 ± 0.2, 23.54 ± 0.2, 28.44 ± 0.2, 39.44 ± 0.2.

3. A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following X-ray powder diffraction data: (2θ):4.86± 0.2,14.10 ± 0.2, 14.90 ± 0.2, 19.35 ± 0.2, 22.20 ± 0.2, 23.04 ± 0.2, 23.54 ± 0.2, 28.44 ± 0.2, 39.44 ± 0.2.; a DSC exotherm at 194. 93°C (onset at 189.42°C) and one endotherm at 87.83°C, 144.03°C and 251.26°C and a water content of between 11.0 to 12.5% by weight as determined by titration according to Karl Fischer.

4. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, having a DSC exotherm at 194. 93°C (onset at 189.42°C) and one endotherm at 87.83°C, 144.03°C and 251.26°C.

5. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.

6. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.

7. The S-(-)-9- fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according

to claim 1, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

8. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

9. A process for the manufacture of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate comprising the steps of:

a) heating a suspension of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate in an organic solvent and water at 70-80°C to obtain a clear solution;

b) cooling the solution to provide a crystalline substance;

c) isolating the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at 30°C - 35°C by filtration or centrifugation;

d) air drying of the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at a temperature between 30°C - 35°C.

10. A process according to claim 9, wherein the organic solvent is acetone or acetonitrile.

11. The process according to claim 9 wherein the organic solvent is acetone.

12. A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 and a carrier, diluent, solvent or excipient.

13. A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 and a carrier, diluent, solvent or excipient.

14. A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate according to claim 3 and a carrier, diluent, solvent

or excipient.

15. A method for treating a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal in need thereof.

16. A method for treating a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal in need thereof.

17. A method for treating a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal in need thereof.

18. A method for preventing a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal at risk of being infected.

19. A method for preventing a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal at risk of being infected.

20. A method for preventing a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal at risk of being infected.